



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1105

[Docket No. FDA-2016-N-1555]

Refuse to Accept Procedures for Premarket Tobacco Product Submissions; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the Federal Register of August 8, 2016, a direct final rule regarding procedures for refusing to accept premarket tobacco product submissions. The comment period closed October 24, 2016. FDA is withdrawing the direct final rule because the Agency received significant adverse comment. FDA will consider the comments we received on the direct final rule to be comments on the companion proposed rule published at 81 FR 52371 (August 8, 2016).

DATES: The direct final rule published at 81 FR 52329 (August 8, 2016), is withdrawn effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Paul Hart, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on August 8, 2016, (81 FR 52329) is withdrawn.

Dated: November 9, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

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